DRUG UTILIZATION REVIEW BOARD
Meeting Minutes, Open Session
Kansas University Memorial Union-English Room
Lawrence, Kansas
May 8, 2002

Members Present: Dr. John Whitehead, Chair, Dr. Jim Backes, Linda Frey, Kathy Miller-Lemke, Dr. Brenda Schewe, Janette McMillan

Kansas Medicaid DUR Program Staff Present: Karen Braman, Diane Hack

SRS Staff Present: Bob Day, Mary Obley, LouAnn Gebhards, Nialson Lee

BCBS Staff Present: Linnae Luebbe, Karen Kluczykowski, Dodie Greenfield

FirstGuard Health Plan: Dr. William Pankey, Medical Director

Representatives: Barbara Belcher (Merck), Russell Norris (Merck), Kevin Rose (Merck), Brett Spencer (Purdue), Kathleen Carmody (Lilly), Mark Mlynarceyk (Hoffmann-LaRoche), Andrea Harshberger (G.S.K.), Mike Hutfles (Pharmacia), Tom Knox (Pharmacia), Myrle Myers (Johnson & Johnson), David Lindquist (Janssen), Gary Pederson (Bayer), Tammie Capps (Purdue), Kate Kulesher (Wyeth), Beth Nelles (Abbott), Dick Knoespel (Abbott)

I. **Call to Order:** The Open Meeting of the Drug Utilization Review Board was called to order at 9:40am by Dr. John Whitehead, Chair.

II. **Approval of the Minutes:** The January DUR Board and March DUR/PERC meeting minutes were approved without changes. The motion to approve was made by Linda Frey and seconded by Kathy Miller-Lemke. Motion carried.

III. **Old Business:**

A. Medicaid Preferred Formulary/Legislative Update

Discussion- Bob Day, Ph.D, Medical Policy and Medicaid Director, Kansas Department of Social and Rehabilitative Services (SRS), gave the legislative update including a budget update. Because Mr. Day was here for the beginning of the meeting, he provided the legislative update in addition to the review of old business on the Medicaid preferred formulary. Several bills were proposed during the legislative session to reduce expenditures with the goal of minimal effect on the beneficiaries. Bob Day explained that Medicaid can be described as two types of programs, with two main user groups. The first group consists of an insurance program for the poverty level enrollees including many pregnant women and

children. This group has low health care costs. The second group includes those at the poverty level with significant health problems. Some of those people are in nursing homes with a high number of prescriptions. Another part of this group is a high utilization group. This group has high in patient costs but low pharmacy costs. A nurse case management model for an identified group of the most expensive users is being developed by SRS. This model may be ready by October 2002. The estimated budget savings from a case management program are around four to five million dollars annually.

Senate bill 603 was discussed. This bill was designed to negotiate supplemental pharmacy rebates and institute a Medicaid preferred drug list (PDL). SRS would have the ability to PA drugs not on the PDL. According to the bill, in cases where drugs within a therapeutic class have the same efficacy, safety, and effectiveness, then pricing should be taken into account when there is a difference in the net cost. A provision has been added to the bill to require a "dispense-as-written" over-ride. Mental health drugs were excluded.

The Kansas Medical Society, DUR Program and Kansas Pharmacists Association were asked to submit nominations for a formulary committee created by SB 603. The PDL committee will be given a list of drug classes to review and background material, including relevant peer-reviewed articles. The committee will make recommendations to the DUR Board on drugs to include in a PDL. It is essential that patient care is not compromised. Regarding the current budgetary situation, twenty-five million dollars have been cut from the FY 2003 drug budget.

A proposal regarding nursing homes has been made. It involves a person centered plan of care for the residents. Other agencies have control over this. Some of the reductions are not realistic. Dispensing fee changes are coming. The proposal is that reimbursement to pharmacies will be reduced from the current AWP-10% + $4.50 to AWP-14% for brand name and AWP-25% for generics, plus a $4.00 dispensing fee. Pharmacists will need to be involved in this. Significant cuts in the budget will be made. The upcoming health care crisis is increasing.

The AIDS Drugs Assistance Program (ADAP) will become SRS' responsibility. The ADAP was the responsibility of Kansas Department of Health and Environment (KDHE), who maintain the gate-keeping program. This is a good opportunity for SRS to work with KDHE. The goal is to use some of the purchasing expertise of the Medicaid Pharmacy Program.

Kathy Miller-Lemke asked if the copay was raised. Bob Day replied that the copay has been increased from two to three dollars per prescription. Karen Braman asked if the ADAP program was completely federally funded or if there was a state match. Bob Day replied there was some state money but did not have the exact percent state/federal match. Janette McMillan asked about developing a step formulary for the state hospitals for mental illness. She commented that Texas has an algorithm for antipsychotics that has been effective. Colorado has

been reviewing the step plan that Texas uses. Bob Day commented that he does not want people go through the process of failure to get to the right drug for mental illness. He commented that it is difficult to get the state hospitals to use generic drugs.

Karen Braman clarified that individual drug pricing would be available to the PDL committee members, however it is confidential information and cannot be discussed during open session meetings. Karen Braman asked if the SSRIs are a closed issue. Bob Day stated that a heavy discussion with physicians and a more voluntary approach will be taken with this class. The question was asked if the prior authorization criteria could be more readily available. Karen Braman responded that it could easily be made more available either by having a list on the web site or a hard copy sent out to physicians. Bob Day commented that prescribers need to be more involved in pricing health care not just Medicaid, but the whole system. Dr.Whitehead asked how many members will be on the formulary committee. Karen Braman responded that the language is still in draft. SRS has received nominations from the DUR Board and is awaiting nominations from KMS and KPhA.

B. Oxycontin® Quantity Limit & Review of PA Criteria

Discussion-Karen Braman discussed that during the March DURB/PERC meeting, the recommendation from both committees was to limit Oxycontin® to 480mg/day. The current PA criteria for exceeding narcotics quantity/dose limits were not available at the meeting. Dr. Bob Twillman, KUMC Cancer Center, volunteered to review the criteria along with Dr. Wayne Wallace, SRS. Karen Braman asked for changes or comments from the DUR Board. Mary Obley replied that Dr.Wallace had no changes. Dr. Twillman suggested propoxyphene be removed from the formulary because of its ineffectiveness and potential for cardiotoxicity. Another change suggested by Dr. Twillman was putting limits on Stadol® and Ultracet®. When this was looked into, it was found that both drugs currently have quantity limits. Oxycodone and morphine currently do not have limits. Dr.Whitehead asked if these drugs should be added to PA criteria listing. Karen Braman suggested that the listing on criteria limits be updated. Dr. Backes suggested working backwards from the Oxycontin® limit to calculate the morphine limit. Dr. Pankey, Medical Director for FirstGuard Health Plans, suggested referring to a pain management specialist for input. Karen Braman commented that Dr. Twillman had been involved since before the March meeting. Dr. Schewe commented that over 480 mg/day of Oxycontin® requires a PA. Dr. Pankey commented that higher and higher doses for pain is not effective. The patient may feel that care is being withheld if not receiving higher dosages of pain medication. Karen Kucykowski, BCBS, asked for a clarification on the Oxycontin® limit and asked if this included immediate release oxycodone. The DUR Board recommended getting input from the pain management specialist on IR oxycodone in addition to morphine.

Recommendation- The DUR Board recommended adding a quantity limit to morphine and consulting a pain management specialist to assist with revising the PA criteria.

Action- Motion to approve by Dr. Whitehead, seconded by Dr. Schewe. Motion carried.

IV. Program Director's Report

A. 1st Quarter 2002 Activity (Profiles, Intervention, Bulletin)

Discussion-Karen Braman discussed first quarter 2002 activity report. Intervention letters regarding the Serzone® black box warnings were sent to prescribers in February 2002. A total of two hundred forty nine letters were sent out. There was a twelve percent response rate, with almost all responses positive. A check box was added to the form if the physician wanted safety-related information in the future. The forms were all returned with this box checked and many had positive hand written comments.

Profiles were sent out in April for polypharmacy in the nursing home elderly and stimulants in children under age five. Three hundred profiles were reviewed. Only twenty intervention letters were sent to prescribers. The next profile will focus on high-dose risperidone in the elderly and ziprasidone drug interactions.

On April 19th Karen Braman gave a presentation on atypical use in the Kansas Medicaid population to the medical staff of Community Mental Health Centers in Kansas at their annual spring meeting in Salina. It was well received. The majority of atypical use is outside of schizophrenia and is increasing in use for behavioral disorders and conduct disorders. At any one time, thirteen to fourteen thousand Kansas Medicaid patients are on atypicals. Dr. Burke has been asked for input on focus areas for DUR intervention with this drug class.

On May 14th, Karen Braman will give a joint presentation about asthma care in Kansas Medicaid with Dr. Pankey, FirstGuard Health Plan, who will be presenting on FirstGuard's asthma data and asthma disease management program.

The DUR annual report is due to the Centers for Medicare and Medicaid Services (CMS) by the end of June. Karen Braman asked for suggestions or comments in regard to this report. The report is a way for CMS to get information on each state DUR program. Dr.Whitehead asked if the format is dictated by CMS. Karen Braman replied that CMS does dictate the format. The survey is available electronically now. Dr. Whitehead asked for comments on the legislative update. No comments were made.

V. New Business

A. Coverage of Anti-Obesity Therapy

Discussion-Karen Braman commented that since the March DUR/PERC meeting, Blue Cross staff have been pulling data from the prior authorization unit on Xenical® and Meridia®. After looking at individual patient data, it is apparent that some beneficiaries have lost weight on the drugs. SRS does not want to deny access to those people who can benefit from the drugs. Nialson Lee commented that the PA criteria are not very clear when looking at the data, and he would like for the DUR Board to review the PA criteria. Mary Obley replied that she spoke with Dr. Early. He suggests removing the absolute contraindication of SSRIs with Meridia®. Karen Braman commented that Dr. Early has volunteered his involvement in making recommendations for the criteria. Karen Braman and Mary Obley will set up a conference call with Dr. Early. Dr. Schewe commented that there is an initial weight loss, and then there is a plateau period. There is a 5% weight loss requirement in the PA criteria. Karen Braman asked how the criteria could be structured so it is tighter and clearer. Dr. Schewe responded that if patients are not gaining weight then this is successful for some. Karen Braman commented that there is a vast number of patients on atypicals who are gaining weight. Maybe this should be added as a criteria. The criteria needs to be more individualized. Dr. Backes added that some people are successful if they lose 5% from the baseline and sustain that loss which may prevent diabetes and hypertension. Dr. Whitehead commented that not too many people are on the drug for more than a year. Renewals drop off after a year on those that are not losing weight. He suggested that criteria should be developed for that. Mary Obley replied that out of one hundred ninety six initial requests for the drug, three patients are still on it after eighteen months. Dr. Schewe commented that it is successful if the patient does not regain all of the weight back. Dr. Whitehead suggested developing criteria after the patient has been on the drug for one year. Dr. Pankey asked how many patients have had gastric bypass surgery covered by Medicaid. SRS responded that they would check into this and report back to the committee.

B. Public Comment from Pharmaceutical Manufacturers on Anti-Obesity Therapy

Discussion-Mark Mlynarczyk, Roche, discussed the XeniCare Program®. Clinicians with an average of twelve years of experience staff the program. A nurse talks to the patients and consults with them regarding any questions or concerns they may have. Patients have more positive results with this program. Karen Braman asked if the follow-up phone calls are initiated by the patient. Mark Mlynarczyk responded that this is decided on a case-by-case basis. Biweekly newsletters about managing diet are sent to the patient. Dr. Schewe asked at what grade level the newsletters are written. Mark Mlynarczyk replied that it serves

Medicaid patients. Karen Braman brought up HIPAA and the issue of treatment versus marketing. Mark Mlynarczyk commented that a portion of the information focuses upon Xenical®.

Beth Nelles, Abbott, discussed their program for Meridia®, which is similar to the program for Xenical®. Patients receive newsletters and diet and exercise counseling. Fifty percent of patients on the program have a five percent weight loss. The SSRI warning has changed so patients don't have to go off their SSRI to receive Meridia®. The maintenance program is an important part of the Meridia® Program. Dr. Pankey asked how much the patient risk profile changed from where they started. He commented if the risk hasn't changed then it is not of value to the patient. Dr. Schewe commented that it is hard to conduct studies when data is not available from hospitalizations, etc. Ms. Nelles recommended tracking patients prospectively.

Action- Karen Braman asked for a vote to remove the SSRI contraindication from the obesity drug PA criteria. The motion was made by Dr. Schewe and seconded by Janette McMillan. Motion carried. Karen Braman and Mary Obley will have a conference call with Dr. Early to get his recommendations on the PA criteria and will report back at the July meeting.

C. Develop Schedule for FY2003 Drug Utilization Reviews

Discussion- Karen Braman discussed a suggested schedule for drug utilization reviews during fiscal year 2003 and asked the DUR Board for their recommendation on focus areas for DUR intervention. Topics suggested for the profiles and bulletins included the atypicals, the preferred drug list, narcotics and anticonvulsants. Research projects in the future include looking at macrolide resistance patterns. Dr. Pat Howard and Dr. Theresa Shireman will be studying Ace inhibitor and beta-blocker use in congestive heart failure patients. Psychotropic use in the elderly is another research project Dr. Shireman will be working on this summer. Dr. Whitehead mentioned that some patients are using two atypicals. This may be a topic to focus on. Other topics include Seroquel® use for sleep, and high dose Risperdal® in the elderly and Geodon® drug interactions. Janette McMillan commented on dual atypical use as a focus, as well as use in young children. Dr. Whitehead suggested looking at quinolones. Janette MacMillan suggested that the fourth quarter bulletin cover obesity because more data will be available by then. Dr. Schewe suggested looking at the quinolones along with macrolide resistance. Karen Braman suggested looking at appropriate antibiotic use in general as well.

D. Other New Business

Discussion-Mary Obley commented that SRS is reviewing drugs on PA. There is a PA in place for Viagra®, with a quantity limit of 4 tablets per month. She asked

whether the PA should be removed. Karen Braman commented that the total expenditures are about $40,000 a year for Viagra®.

Action-Dr. Schewe made a motion to remove the PA on Viagra® and keep the POS quantity limit. Janette McMillan seconded. Motion carried.

VI. Other:

Discussion-Dr. Schewe asked about review of DUR criteria. Karen Braman mentioned that the ACS contract allows querying claims data, but ACS does not include DUR criteria. However, the DUR Board will still review prospective DUR (pro-DUR) criteria from the state POS system. Karen Braman will get a pro-DUR report from the state.

The COX-2 utilization patterns article written by Nicole Schlobolm and Karen Braman was published in the March 2002 Kansas Physician Journal.

VII. Public Comment:

Discussion-Tammie Capps, Purdue Pharma asked if a limit of one provider for Oxycontin® was considered lock-in and asked what the criteria for lock-in are. Karen Braman responded that this is not lock-in but a requirement that the patient's Oxycontin® be prescribed by only one physician. This restriction was included in the narcotics criteria due to the problem of patients using multiple prescribers to obtain narcotics. Tammie also asked if the DUR Board would consider adding moderate pain and post-surgical pain to the PA criteria for Oxycontin®. The DUR Board discussed that PA is required only for Oxycontin® doses over 480mg/day and that this level of dosing should not be necessary for moderate or post-surgical pain. Ms. Capps also asked if the DUR Board would consider allowing prescriptions for over 480mg/day of Oxycontin® to be filled for a three month grace period in order to give the physician time to obtain PA. The DUR Board discussed this and felt that a grace period was not necessary. Dr. Schewe commented that if the patient is using the drug appropriately then a three month grace period is not necessary. Dr. Whitehead mentioned that he had not heard of problems with getting PA. He commented that Oxycontin® is appropriate for lower back pain and neuropathic pain. Ms.Capps asked if ICD-9 codes are required with pain diagnosis. Karen Braman responded that this is not an automated process and that specific ICD-9 codes are not required.

VIII. Adjourn to Executive Session:

There being no further discussion, it was moved by Dr. Whitehead to adjourn to Executive Session. Motion carried. During the Executive Session of the DURB meeting, specific cases involving providers and/or beneficiaries are discussed and are thus protected by privacy laws. The open meeting was adjourned at 11:38a.m.